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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/017,471

10/23/2001

Eriko Takano

0380-P02329US1

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7590

08/18/2005

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EXAMINER

NASHED, NASHAAT T

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 08/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/017,471

Applicant(s)

TAKANO ET AL.

Examiner

Nashaat T. Nashed, Ph. D.

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,9,11,13,15 and 20-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,9,11,13,15 and 20-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 20, 2005 has been entered.

The application has been amended as requested in the communication filed June 6, 2005. Accordingly, claims 1, 9, 11, 13, 15, and 20 have been amended, and claims 2-8, 10, 12, 14, 16-19, and 24-32 are canceled.

Claims 1, 9, 11, 13, 15, and 20-23 are pending and under consideration.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. The genes *scbA* and *scbR* from *S. coelicolor* are disclosed in the application, and thus, should be accompanied by sequence identification number at each occurrence in the specification and the claims, see for example page 4, lines 13 and 35, page 5, line 21, page 6, line 24, and page 7, lines 27-30 as well as the Figure description 4(b), and 9-14. From page 11, line 35 through page 12, line 27, there are several nucleic acid sequences which are not identified by a sequence identification number as well as a reference the amino acid sequence of *scbR* as shown in Figure should be accompanied by a sequence identification number. Also, pages 34-39 contain several nucleic acid sequences, which are not identified with sequence identification number. The above-mentioned examples of non-compliance with the sequence rules are exemplary only, and do not represent an exhaustive search through out the specification of all incidents of non-compliance with the sequence rule. Applicants must search their application for all incidents of non-compliance, and perfect their compliance with the sequence rules.

Claim 15 and 20 are objected to because of the following informalities: (a) The symbol © should be replaced with (c), and (b) Claim 20 is dependent from canceled claim 19. For examination purposes only, claim 20 is assumed to be dependent on claim 15. Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

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Claims 1, 9, 11, 13, 15, and 20-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following are the reasons for the rejection:

- (a) Claims 1, 9, and 15 contain the phrase "scbA gene" of *Streptomyces coelicolor* without being identified with a sequence identification number. The gene is disclosed in the specification having a specific sequence identification number. The product of the gene is not disclosed to have a specific activity other than that the deletion of the gene allow the enhanced production of act and Red, but not other polyketides based compounds and antibiotic. For examination purposes only, the gene is assumed to be the complement of residues 2142-1199 of SEQ ID NO: 19 and the product of the said gene is SEQ ID NO: 17
- (b) The phrase "capable of specific hybridization" in claim 15 renders the claim indefinite. The specification does not define the phrase, and one of ordinary skill in the art would not know its meaning. In fact, the phrase could not be found in the specification. Thus, one of ordinary skill in the art would not know the metes and bound of the claimed invention.
- (c) Claims 11, 13, and 20-23 are included because they are dependent on one of the rejected claims and do not cure their deficiencies.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Item (c) is a new matter. The amendment does not appear anywhere in the specification. Applicant may cancel the claim, or amend the claim to remove the new matter to overcome this rejection. Also, the negative limitation containing *S. griseus* is not found in the specification.

Claims 1, 9, 11, and 13 are directed to a method of modifying a strain of *S.* Claims 1, 9, 11, and 13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 9, 11, and 13 are directed to a method of modifying a strain of *S. coelicolor* by disabling any gene named *scbA*. The result of disabling said gene is an enhanced production of antibiotic known as Act or Red. The specification, however, only provides a single representative species from *S. coelicolor* having, presumably, the nucleic acid sequence of residues 2142-1199 encompassed by these claims. Also, the specification teaches that *scbA* gene is known by different name and structure and its expression has different effect on the production of antibiotics in different species. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these DNAs by any identifying structural characteristics or properties other than the activities recited in claim 1, for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention. The insertion of a sequence identification number after the name of the gene would obviate this rejection.

Claims 15 and 20-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are broader than the enablement provided by the disclosure with regard to disabling *scbA* in any *streptomyces* sp. Factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claimed invention encompasses a method of identifying any *Streptomyces* sp. in which disabling a homologous gene would lead to enhanced production of antibiotics. The specification provides guidance and examples in the form of an assay to isolate the nucleic acid sequence of SEQ ID NO: 19 and the open reading frame for the amino acid sequence of SEQ ID NO: 17 (examples 1). While molecular biological techniques and genetic manipulation to disable any genes are known in the prior art and the skill of the artisan are well developed, knowledge regarding the nucleic acid of the *scbA* gene and the amino acid sequence encoded thereby in most *Streptomyces* sp. and the biological function of the *scbA* gene and its role in the production of antibiotics is lacking. Thus, searching *scbA* gene in any *Streptomyces* sp. wherein the gene product has 35%, 50%, 65%, and 80% amino acid

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sequence homology to SEQ ID NO: 17, and disable said gene in the *Streptomyces* sp. from which the gene is isolated to identify the effect of disabling the gene on the particular antibiotic of interest is well outside the realm of routine experimentation and predictability in the art of success is extremely low. It should be first that a gene could not be disabled by known method, unless the ordinary skill in the art knows the gene. The amount of experimentation to identify *scbA* gene is enormous. Since routine experimentation in the art does not include screening vast numbers of genomic libraries and deleting a native gene, where the expectation of obtaining the desired effect on the production of antibiotic is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding which antibiotic are enhanced upon disabling *scbA*, the nucleic acid sequence of *scbA* gene. Without such guidance, the experimentation left to those skilled in the art is undue.

Allowable subject matter:

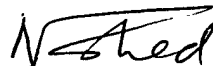
Claims 1, 9, 11, and 13 would be allowable if they are amended to overcome the rejection under 35 USC 112, second paragraph and the insertion of a nucleic acid which is the complement of the nucleic acid sequence of residues 2142-1199 of SEQ ID NO: 19.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen M. Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nashaat T. Nashed, Ph. D.  
Primary Examiner  
Art Unit 1656